

## PROTECTING AMERICANS LIVES ACT (PAL) ACT OF 2022

Congresswoman Yvette Herrell's legislation requires the Food and Drug Administration to produce a report and recommendations on regulatory barriers to domestic manufacturing of medical products, including the active pharmaceutical ingredient of finished drug products, that are critical to public health during a public health emergency.

### PROTECTING AMERICANS LIVES ACT (PAL) ACT OF 2022

This legislation requires that no later 180 days after passage the Commissioner of Food and Drugs submit to Congress a report on barriers, including regulatory inefficiencies, to domestic manufacturing of active pharmaceutical ingredients, finished drug products, and devices that are imported from outside of the United States that are considered critical to public health during a public health emergency declared by the Secretary of Health and Human Services.

The report must identify:

- Factors that limit the manufacturing of active pharmaceutical ingredients, finished drug products, and devices;
  - Specific strategies to overcome the challenges identified.
  - The Secretary of Health and Human Services may then implement the strategies recommended to the extent possible under law.

### BACKGROUND

The global pandemic has revealed how fragile our nation's supply chain has become, reliant on the Chinese Communist Party for much of our medicine and medical devices.

There is bipartisan agreement that this must end, and lifesaving drugs and medical devices needed to confront public health emergencies must be manufactured in the United States.

The first step to rebuilding America's domestic drug and medical device capability is to identify the government barriers and regulations that hinder American business from producing life-saving products at home.

This is a national security issue: According to Rosemary Gibson, azithromycin, ciprofloxacin, and piperacillin/tazobactam, the three most used antibiotics, rely exclusively Chinese-manufactured ingredients.

Every day medicines are overwhelmingly imported from China as well, including 95 percent of ibuprofen and 70 percent of acetaminophen consumed in the United States.<sup>2</sup>

Pharmaceuticals are a large portion of our economy. The U.S imported \$128 billion in pharmaceuticals, the third largest category of imports, in 2019.<sup>3</sup>

According to economic modeling by CPA, increasing U.S. pharmaceutical production to 2010 levels or just \$66 billion would increase US GDP by \$200 billion and result in 804,000 more American jobs.<sup>4</sup> These are good paying jobs with a median income of \$74,890 in the U.S. with a 47% higher than the median private sector salaries.<sup>5</sup>

This report will provide a path forward to fixing this problem. First, our nation should re-shore vital medicine and then begin rebuilding our U.S. manufacturing to protect our nation's security and health. This report is a first step to figuring out a roadmap to pharmaceutical independence.

<sup>1</sup> Testimony of Rosemary Gibson, Author, China Rx: Exposing the Risks of America's Dependence on China for Medicine Before the Senate Committee on Small Business and Entrepreneurship, "The Coronavirus and America's Supply Chain," March 12, 2020.

<sup>2</sup> Doug Palmer and Finbarr Bermingham, "U.S. policymakers worry about China 'weaponizing' drug exports," Politico, December 12, 2019.

<sup>3</sup> Jerry Ferry, "It's Time to Rebuild Domestic Drug Production in the US, for Both Health and Economic Reasons," Industry Week, March 17, 2020.

<sup>4</sup> Ibid.

<sup>5</sup> Ibid.